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VENABLE LLP
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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/849,229

Applicant(s)

MAHADEVAN ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
4a) Of the above claim(s) 1, 2 and 9 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 3-8 and 10 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/20/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending.

Preliminary Amendment

The Preliminary Amendment filed May 20, 2004, has been received and entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 20, 2004, was received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

Applicant's election of Group II, claims 3-8 and 10, in the reply filed on November 6, 2006, with traverse is acknowledged. However, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). With respect to comments drawn to an election of species it should be noted that any such election was referred to in the alternative and that an election of an invention was requested which Applicants did elect an invention. Applicants are correct there is no election of species nor was there an intention of one but the language referred to an election of species in the alternative while requesting an election of an invention. Therefore, Applicants election of invention of Group II as noted above is respectfully acknowledged.

Claims 1-2 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or

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linking claim. Election was made **without** traverse in the reply filed on November 6, 2006.

Claim Objections

Claim 10 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is suggested that claim 10 be canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rendered vague and indefinite for the recitation of "having a molecular weight in the of 31000 to 32000" at line 2. The claim is grammatically indefinite and vague since the term range is not recited and hence it is suggested to insert —range— before "of" and after "the" in line 2. Also "the cell" and "the cell supernatant" recited at lines 7-8 lack antecedent basis. Further, the recitation of "1,00,000" is confusing

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because the obvious typographical does not make clear whether 100,000 or 1,000,000 is intended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balaraman et al (US 5,434,059), recited on enclosed PTO-1449 Form in view of Mitzutani (US 4,009,264) and Hanson et al (5,700,669), both recited on enclosed PTO-892 Form.

Claims are drawn to a process for preparation of thrombolytic enzyme, Thrombinase.

Balaraman et al teach a process for preparation of thrombolytic enzyme, Thrombinase, see abstract. The process comprising culturing *Bacillus sphaericus* serotype H5a5b, see abstract, on a well known culture medium. Further, comprising removing cells, see column 2, line 55, performance of two step ultra filtration, see column 2, line 59, using molecular weight cut off membrane filters of 10,000 molecular weight (mw) and 30,000 mw, see column 5, lines 6 and 8. Also salting out with ammonium sulphate, note column 2, line 63, is performed. Further, dialysis and reconstituting buffer and dialysis steps are carried out as well, note column 3, lines 5-10 and lines 61-65. Decolorizing is also performed, note column 3, line 59. In addition, purifying is performed by ion exchange chromatography by gel filtration, note column 3, line 16. Thrombinase is, therefore, obtained note column 4, lines 23-35.

The claims differ from Balaraman et al in that the culture medium and the step of re-precipitating the precipitate using ice-cold acetone and thrombinase having a molecular weight range of 31,000-32,000 are not disclosed.

Mizutani teaches reaction product can be collected by precipitation with acetone and further, by repeating a cycle of dissolving precipitate in water for example, and reprecipitating it from acetone, the precipitate can be purified. Note column 9, lines 60-67.

Hanson et al teach a culture medium for microorganisms, and further, *Bacillus sphaericus* is disclosed, note column 6, line 54. *Bacillus* species are cultivated in medium comprising beef extract, peptones, sodium chloride, note column 7, lines 36-45.

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Furthermore, other ingredients for culture medium are disclosed which include sodium acetate, yeast extract, ammonium sulfate, etc., note column 9, lines 10-40.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the process steps of Balaraman et al using the reprecipitating step in ice-cold acetone and culture medium of Mizutani and Hanson et al, respectively because acetone is known to be used for purifying enzymes and the culture medium is well known to be useful for *Bacillus* species. The art clearly recognizes the usefulness of the reprecipitating step in acetone for purifying an enzyme as taught by Mizutani and for culturing *Bacillus* species in a culture medium as taught by Hanson et al.

Balaraman et al clearly teach culturing the *Bacillus sphaericus* serotype H5a5b in a well known culture medium of which Hanson et al clearly do teach and demonstrate to be well known. Hanson et al describe a culture medium which contains all of the same ingredients as claimed. To select soya peptone is clearly within the skill of an artisan. To obtain a Thrombinase between the range of 31,000 to 32,000 molecular weight is also well within the purview of an ordinary artisan. Therefore, although Balaraman et al identify a thrombinase of 18,500 molecular weight one of skill would have been motivated to obtain other thrombinase enzymes to enhance results of their process.

The pH is clearly recognized by the cited prior art and to vary the range of ammonium sulphate is a matter of selective optimization of the cited prior art and well within the skill of an ordinary artisan. Further, to provide for a selected ratio of acetone

and crude enzyme is also within the skill of an ordinary artisan. Thus, each of the claimed features are taught or are at least suggested by the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Deborah K. Ware

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PATENT EXAMINER

Deborah K. Ware
January 20, 2007